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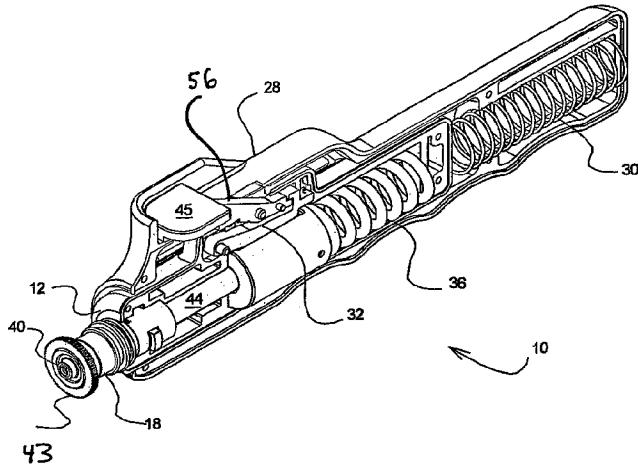
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(54) Title: NEEDLE-LESS INJECTOR

(57) **Abstract:** A needle-less injector device that includes an outer housing and an inner housing that is slideably supported from the outer housing is disclosed. The inner housing supporting a vial that includes a nozzle for delivering a fluid held within the vial. A spring powered ram that is adapted for pushing a seal and plunger is mounted within inner housing. A skin tensioning spring mounted between the inner housing and the outer housing is used for pushing the leading end of the inner housing away from the outer housing. A trigger that cooperates with the spring powered ram is used to release the ram from the cocked position only when the inner housing is in a firing position.

WO 2006/118616 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

NEEDLE-LESS INJECTOR

RELATED APPLICATIONS

The present application is related to allowed U.S. Patent Application Serial No. 10/158,853, entitled "Needleless Injector and Ampule System," filed May 30, 2002 and U.S. Patent Application Serial No. 11/185,736, entitled "Needleless Injector and Ampule System," filed July 21, 2005.

BACKGROUND OF THE INVENTION

(a) Field of the Invention

This invention generally relates to a needle-less injector for delivering a dose of liquid into the inner housing of a human or animal. More particularly, but not by way of limitation, to a spring actuated needle-less injection device that delivers a high-pressure jet of fluid through the epidermis of the human or animal.

(b) Discussion of Known Art

The advantage of needle-less injection devices has been recognized for some time. Some of these advantages include the absence of a needle that presents a hazard to healthcare workers, the risk of cross-contamination between humans or animals is reduced, the risk of needle breakage in the tissue of the human or animal is eliminated, the jet is generally smaller than the diameter of a hypodermic needle and thus is less painful than a hypodermic needle.

Because of the well-known advantages of a needle-less injection device, there are many pneumatic or gas actuated needle-less injection devices that are designed to provide multiple doses to patients or animals. Most known needle-less injection devices operate by using a piston to drive the fluid to be delivered through a fine nozzle that creates a small, high pressure stream that penetrates the skin simply due to the high pressure. Multi-dose devices depend on a source of air or working fluid that is used to operate the piston that drives the fluid through the nozzle. Thus, a serious limitation of these devices is that they must have a readily available source of air or other fluid to drive the piston. This makes these devices impractical for use in the field conditions of remote areas and inconvenient in hospitals or clinics.

Because of the disadvantages of injection devices that use high-pressure fluids to drive the piston, a great deal of attention has been given to the development of a spring-

powered needle-less injection device. The success of known devices has been limited, however, due to problems associated with safety and reliability. The issues regarding safety generally involve the possibility of accidental discharge of the device. And the problems of reliability generally involve the device's ability to deliver a full, known dose of the liquid being delivered into the animal or human.

Safety issues generally arise in association with devices that have exposed triggers or include a ram or piston driving device that can extend beyond the inner housing of the injector. The risk of using this type of device is similar to the risks associated with the triggers on firearms, and that is the inadvertent pressing of the trigger, causing the accidental or premature firing of the device.

Reliability issues include a broad spectrum of problems. One significant problem is the creation of a suitable jet or stream of fluid and the introduction of this jet on to the skin of the animal or human. Preferably, the jet will be a very fine jet that will impact a section of taught skin at an angle of incidence of preferably 90 degrees. Most of the energy of the stream is used to penetrate the skin when the jet impacts the skin at 90 degrees to the skin. Additionally, by keeping the skin taught prior to delivering the jet of fluid, the skin is not allowed to flex, and thus more of the energy from the jet is used to penetrate the skin rather than deflecting or moving the skin.

Therefore, a review of known devices reveals that there remains a need for a spring-operated injection device that prevents firing until the device is properly positioned against the skin.

There remains a need for a hand-held, spring operated needle-less injection device that will ensure that the skin is held taught and that the nozzle that is to deliver the jet is held at 90 degrees to the skin prior to allowing the jet to be delivered to the skin.

SUMMARY OF THE INVENTION

It has been discovered that the problems left unanswered by known art can be solved by providing a hand-held, spring-powered, needle-less injector device that includes an outer housing; an inner housing that is slideably supported from the outer housing, the inner housing being movable along the outer housing from a ready position to a firing position, the inner housing having a leading end and a trailing end, the leading end of the inner housing being adapted for accepting a vial that includes a nozzle for delivering a fluid held within the vial, the inner housing further having a spring powered ram that is movable from a cocked

position to an unloaded position; a skin tensioning spring mounted between the inner housing and the outer housing, the skin tensioning spring biasing the leading end of the inner housing away from the outer housing; and a trigger, the trigger operable through the outer housing when the inner housing is in the firing position, the trigger cooperating with the spring powered ram to release the ram from the cocked position only when the inner housing is in the firing position.

According to a highly preferred embodiment of the invention a trigger stop is incorporated into the outer housing and the trigger is mounted from the inner housing. The trigger stop prevents operation of the trigger when the inner housing is not in the firing position. An example of this trigger stop includes a protrusion that extends from the outer housing and impedes the movement of the trigger when inner housing is not in the firing position. The protrusion then moves away from the trigger when the inner housing is moved into the firing position.

It is contemplated that the disclosed invention will be used with a vial that includes a connector at one end and a nozzle and a skin tensioner at another end. It is contemplated that the connector will be a bayonet type connector. It is also contemplated that the skin tensioner will be a ridge that surrounds the nozzle.

In operation, the user will position the ram at the cocked position and attach a vial to the leading end of the inner housing. The vial is pre-filled with the liquid that is to be delivered into the animal or human. Then the user presses the nozzle and skin tensioner against the animal or human, causing the inner housing of the device to move against the skin tensioning spring, into or relative to the outer housing to the firing position. Once the inner housing is moved to the firing position, the pressure of the skin tensioning spring is reacted against the animal or human, causing the skin to be stretched taught across the skin tensioner. This stretching of the skin across the skin tensioner will position the target area of the skin at a right angle to the vial and the nozzle. The movement of the inner housing to the firing position also results in the movement of protrusion relative to the inner housing such that the protrusion no longer obstructs the movement of the trigger. The user then simply presses the trigger, which releases the ram, which in turn drives the fluid through the nozzle of the vial and into the animal or human's skin.

It is contemplated that the ram may drive a separate plunger with a seal through the vial to expel the fluid in the vial through the nozzle of the vial. However, the ram may incorporate portions, or all, of the plunger. It is preferred that the ram will drive a separate

plunger and seal will be used since this will enable the design of a one-time use plunger and seal.

Still further, it is contemplated that the use of a separate plunger will allow the use of a mechanical cocking device that will push against the ram to move the ram from an unloaded position to the cocked position.

It should also be understood that while the above and other advantages and results of the present invention will become apparent to those skilled in the art from the following detailed description and accompanying drawings, showing the contemplated novel construction, combinations and elements as herein described, and more particularly defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an embodiment of the device of the present invention, with part of the outer housing removed, so that the inside of the device may be seen.

FIG. 2 is a top view of the device.

FIG. 3 is an exploded view of the device of the present invention.

FIG. 4 is a cross-sectional view of the device of FIG. 1 in the ready position, prior to moving the inner housing into the firing position.

FIG. 5 is a cross-sectional view of the device of FIG. 1 in the firing position.

FIG. 6A is a perspective view of an embodiment of the vial and seal of the present invention.

FIG. 6B is a top view of the vial and seal of in FIG. 6A.

FIG. 7 is a perspective view of a carrying and cocking device for the needle-less injection device of the present invention.

FIG. 8 is a side view of the carrying and cocking device of FIG. 7.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIGS. 1 and 5, a hand-held, spring-powered, needle-less injector device 10 includes an inner housing 12 that includes a leading end 14, and a trailing end 16. The leading end 14 of the inner housing 12 has been adapted to receive a vial 18 that is used to hold a fluid 20 that is to be delivered through the skin 22 covering the tissue of an animal or

human 24 and into the tissue of the animal or human 24. It is important to note that the term "animal" as used herein is intended to include humans as well as other animals.

As illustrated in FIG. 1, inner housing 12 is mounted within an outer housing 28 that slideably supports the inner housing 12. The inner housing is movable from a ready position, illustrated in FIG. 4, to a firing position, illustrated in FIG. 5.

Inner housing 12 can be pushed into the ready position of FIG. 4 by a skin tensioning spring 30 that is mounted between the inner housing 12 and the outer housing 28. The skin tensioning spring 30 plays two primary functions. The first function of the spring 30 is to cooperate with the structure of the vial 18 to pull the animal's skin 22 taught while positioning the skin 22 prior to delivering the fluid 20 into the animal or human 24. The second primary function of the skin tensioning spring 30 is to cooperate with a trigger mechanism 32 to ensure that the device 10 cannot be fired until the device 10 is properly positioned against the skin 22 covering the tissue of the animal or human 24, and the proper amount of pressure or force exists between the vial 18 and the skin 22.

The amount of pressure or force that is used to hold the vial 18 against the skin 22 is an important variable in the injection process. Needle-less injection devices are capable of delivering fluids through the skin 22 of the animal or human 24 by delivering a jet of fluid 34 to the skin 22 at a sufficiently high pressure and velocity so that the jet of fluid 34 penetrates through the skin 22 and into the tissue of the animal or human 24.

Important factors that contribute to the device's ability to accomplish the task of forming a jet of fluid 34 are the amount of energy that can be quickly and efficiently transferred to the jet of fluid 34, and the device's ability to position the jet of fluid 34 such that the energy of the jet of fluid 34 is efficiently used for penetration of the tissue of the animal or human 24. The energy to be transferred to the fluid 20 is stored in an injection delivery spring 36 that drives a plunger and seal 38 into the vial 18 in order to force the fluid 20 through a nozzle 40 that forms the jet of fluid 34. Injection delivery spring 36 is positioned between a head 50 of a ram 44 and the trailing end of inner housing 12.

In order to obtain the most efficient delivery of the jet of fluid 34 into the skin 22 the nozzle 40 should be positioned at a right angle relative to the skin 22 as the jet of fluid 34 is delivered into the skin 22. Delivering the jet of fluid 34 at some angle other than a right angle will mean that a component of the force with which the jet of fluid strikes the skin could be parallel to the skin rather than into the skin 22.

As illustrated in FIGS. 1, 2, and 4-6, the preferred example of the vial 18 will include a skin tensioner 42 that surrounds the nozzle 40 of the vial 18. In the illustrated example, the skin tensioner 42 is a disc 43 positioned approximately about the nozzle exit.

An installation ring 41 has also been shown on the vial 18. The installation ring 41 aids the user in inserting the vial 18 into the device 10 and in positioning the device 10 at a right angle to the skin as the jet of fluid 34 is to be delivered. The skin tensioner 42 may cooperate with the installation ring 41 to pull the skin taught as the device is pressed against the skin prior to delivery of the jet of fluid 34. It has been discovered that a certain minimum amount of force must be applied against the skin in order to ensure that the skin is drawn tight prior to the release of the jet of fluid 34.

The amount of force required to be applied against the skin varies depending on the physical characteristics of the animal being injected with the device 10. For example, an older human may require higher force to hold the skin taut as compared to a young person, simply due to the effects of aging on the elasticity of the skin. Accordingly, it is contemplated that the disclosed invention will be manufactured with different skin-tensioning springs, each skin tensioning spring being of a stiffness that is appropriate for a particular application. It is contemplated that the force imposed by the skin tensioning spring may be made adjustable, for example by adding a threaded plug that screws against the spring to add pre-tension. However, it is preferred that the force imposed by the skin tensioning spring should not be adjustable or replaceable by the end user, but is preferably pre-calibrated during assembly. The outer housing 28 and a cocking and storage mechanism for use with the device 10 will be color coded to inform the user of the pre-set skin-tensioning force for that particular injector device 10.

Thus, in operation the user selects an injection device with the appropriate skin pre-tension spring 30 and injection delivery spring 36, and selects a vial 18 that will contain a desired fluid to be delivered into the tissue of the animal. The vial 18 will be attached to the leading end 14 of the inner housing 12, preferably through the use of a bayonet-type connector, and mated to a seal 38 that may be a part of the plunger and seal 38. The plunger 38 is driven through the vial 18 by spring powered ram 44 that is movable from a safe, cocked position, illustrated in FIG. 4, to an unloaded position, illustrated by dashed lines in FIG. 5. As shown in FIG. 3, the spring powered ram 44 rides within a sleeve 47 that includes a slot 49 for accepting latching components of the spring mechanism 32.

The variation of the skin pre-tension spring 30 and injection delivery spring 36 allows the needle-less injector device 10 to be tailored for a particular application. For example, a needle-less injector device 10 for use on a child would have one particular combination of skin pre-tension spring 30 and injection delivery spring 36, while the combination of skin pre-tension spring 30 and injection delivery spring 36 for an adult male would likely be a different combination. Accordingly, the disclosed invention can be adapted for use on a variety of animals or humans, and for the delivery of a variety of types injections or depth of delivery of the fluid by varying the skin pre-tension spring 30 and injection delivery spring 36.

Referring to FIGS. 1, 3 and 5, outer housing 28 includes an aperture 56. A trigger 45 is mounted in inner housing 12 and protrudes through aperture 56 so as to be engageable by a user. Trigger mechanism 32 includes a link 58 (FIG. 3) that controls the release of ram 44. As can be understood from comparing FIGS. 4 and 5, the firing of the device 10 to deliver a dose of fluid is accomplished by pressing the trigger 32 after the device 10 is in the firing position, illustrated in FIG. 5. However, the trigger 45 of the trigger mechanism 32 can only release the plunger and seal 38 when the device 10 is in the firing position, illustrated in FIG. 5. When the device 10 is in another position (other than the firing position), such as the ready position, the trigger link 58 of mechanism 58 cannot be pressed to release the ram 44. The release of the ram 44 is prevented for safety and for efficacy of the injection.

As illustrated in FIGS. 4 and 5, unwanted activation of the trigger mechanism 32 is accomplished by positioning a protrusion 46 below the trigger 45. The protrusion 46 prevents movement of the trigger 45 in the direction of arrow 48, preventing the release of the ram 44, and thus preventing the firing of the device 10. According to a preferred embodiment of the invention the protrusion 46 extends from the outer housing 28 to a location under the trigger 45. The protrusion 46 is positioned such that it interferes with the movement of the trigger 45 until the device 10 is in the firing position, illustrated in FIG. 5. In the preferred example of the invention, the movement of the inner housing 12 relative to the outer housing 28 moves the position of the trigger 45 (which is mounted from the inner housing 12) relative to the outer housing 28, which holds the protrusion 46.

The amount of movement of the outer housing 28 relative to the inner housing 12 is accomplished against the force of the skin-tensioning spring 30. The stiffness of the skin-tensioning spring 30 is selected such that the appropriate amount of force is imposed against the skin 22 of the animal or human 24. The stiffness of the skin-tensioning spring 30 is

calculated from the well-known formula: $F=k*x$, where F is the required force at the firing position, x is the distance of travel of the inner housing 12 relative to the outer housing 28 to position the device in the firing position (where the protrusion 46 does not impede movement of the trigger mechanism 32), and k is the spring constant of the skin-tension spring 30.

Once the inner housing 12 is positioned relative to the outer housing 28 such that the desired amount of skin tensioning force is applied to the skin 22 against the vial 18, which also positions the device in the firing position, then the pressing of the trigger 45 causes the release of the spring powered ram 44 from the cocked position only when the inner housing is in the firing position.

As can be understood from FIGS. 6A and 6B, the vial 18 will generate the jet of fluid 34 through a nozzle 40. Additionally, the vial 18 includes circumferential stiffening ribs 52 that extend around the body 54 of the vial 18. The stiffening ribs help reduce the amount of deflection of the body 54 of the vial 18 during the delivery of an injection.

Referring to FIGS. 7 and 8, it should be understood that the disclosed system can be used with a combined cocking and carrying device 60. The cocking and carrying device will include cocking ram 62 that is used to push the spring powered ram 44 back to the “ready” position shown in FIG. 4. The cocking and carrying device 60 includes a cradle 64 that retains the outer housing 28 while the cocking ram 62 is pushed against the spring powered ram 44.

The cocking ram 62 will be pushed against the spring powered ram 44 to move the spring powered ram into the “ready” position illustrated in FIG. 4. It should be understood that the cocking and carrying device 60 will cock the needle-less injection device 10 once the device is positioned in the cradle 64 and the cocking and carrying device 60 is closed. Thus, the cocking and carrying device 60 will serve as a cocking device and case for transporting and storing the needle-less injection device 10.

Thus it can be appreciated that the above-described embodiments are illustrative of just a few of the numerous variations of arrangements of the disclosed elements used to carry out the disclosed invention. Moreover, while the invention has been particularly shown, described and illustrated in detail with reference to preferred embodiments and modifications thereof, it should be understood that the foregoing and other modifications are exemplary only, and that equivalent changes in form and detail may be made without departing from the true spirit and scope of the invention as claimed.

CLAIMS

1. A needle-less injector device comprising:

an inner housing having a leading end and a trailing end, the leading end of the inner housing being adapted for receiving a vial that includes a nozzle for delivering a fluid held within the vial, the inner housing further having a spring powered ram that is movable from a cocked position to an unloaded position;

a hollow outer housing adapted for slideably supporting the inner housing, the inner housing moving within the hollow outer housing between a safe position and a firing position;

a skin tensioning spring that is mounted between the inner housing and the outer housing, the skin tensioning spring biasing the inner housing away from the firing position towards the safe position; and

a trigger disposed in said outer housing, the trigger being operable through the outer housing when the inner housing is in the firing position, the trigger cooperating with the spring powered ram to release the ram from the cocked position only when the inner housing is in the firing position.

2. The needle-less injection device of claim 1, further comprising an injection delivery spring positioned between the trailing end of the inner housing and the spring powered ram, wherein when the spring powered ram is moved towards the trailing end of the inner housing the injection delivery is compressed to move the spring powered ram towards the cocked position.

3. The needle-less injection device of claim 2, wherein said skin-tensioning spring has a lower stiffness than said injection delivery spring.

4. The needle-less injection device of claim 3, wherein said skin-tensioning spring and said injection delivery spring are disposed in series within the respective housings.

5. The needle-less injection device described in claim 1 of claim 1, wherein said trigger is mounted from in the inner housing, so that wherein the inner housing and the trigger move together within the hollow gripping person outer housing.

6. A hand held, spring powered, needle-less injector device comprising:
an outer housing;

an inner housing slideably disposed within the outer housing, the inner housing being movable within the outer housing between a ready position to and a firing position, the inner housing having a leading end and a trailing end, the leading end of the inner housing being adapted for receiving a vial that includes a nozzle for delivering a fluid held within the vial, the inner housing further having a spring powered ram that is movable from a cocked position to an unloaded position;

a skin tensioning spring mounted between the inner housing and the outer housing, the skin tensioning spring biasing the leading end of the inner housing away from the outer housing; and

a trigger disposed in said outer housing, the trigger being operable through the outer housing when the inner housing is in the firing position, the trigger cooperating with the spring powered ram to release the ram from the cocked position only when the inner housing is in the firing position.

7. The needle-less injector of claim 6, wherein said trigger is pivotally supported on the inner housing.

8. The needle-less injector of claim 19, wherein said spring powered ram includes a head, the injection delivery spring being positioned within the inner housing between the head and the trailing end of the inner housing.

9. The needle-less injector of claim 8, wherein said trigger cooperates with said head to fix the position of the head when said ram is in the cocked position.

10. The needle-less injector of claim 8, wherein said skin-tensioning spring and said injection delivery spring are positioned in series within the respective housings.

11. The needle-less injector of claim 6, wherein said outer housing includes an aperture that exposes the trigger when said inner housing is in the firing position.

12. The needle-less injector of claim 6, wherein said outer housing includes an aperture that allows a portion of the trigger to be exposed through the aperture when said inner housing is in the firing position and a protrusion that extends from the outer housing, the protrusion impeding movement of the trigger until said inner housing is in the firing position.

13. The needle-less injector of claim 6, wherein said outer housing includes a protrusion that impedes movement of the trigger until said inner housing is in the firing position.

14. The needle-less injector of claim 13, wherein said trigger includes a link that controls the release of the spring powered ram, the link being movable from a first position, wherein the link can cause the engagement of the head whereby the spring-powered ram is locked in the cocked position, to a second position, where the link does not cause engagement of the head and the spring-powered ram is released from the cocked position.

15. A method for delivering a dose of fluid through an area, the method comprising the steps of:

providing a needle-less injector device including an inner housing having a leading end and a trailing end, the leading end of the inner housing being adapted for receiving a vial that includes a nozzle for delivering a fluid held within the vial, the inner housing further having a spring powered ram that is movable from a cocked position to an unloaded position; a hollow outer housing adapted for slideably receiving the inner housing therein, the inner housing being movable within the hollow outer housing between a safe position and a firing position; a skin tensioning spring mounted between the inner housing and the outer housing, the skin tensioning spring biasing the inner housing towards the safe position; a trigger disposed in said outer housing, the trigger being operable through the outer housing when the inner housing is in the firing position, the trigger cooperating with the spring powered ram to release the ram from the cocked position only when the inner housing is in the firing position; and a vial disposed within the inner housing and being adapted for holding the dose of fluid, the vial having an internal cavity that is in fluid communication with a nozzle and a skin tensioner mounted around the nozzle, the ram being connected to a plunger that is adapted to drive the fluid from the internal cavity of the vial and through the nozzle;

placing the skin tensioner against the skin of the area and pressing the tensioner against the area by pushing the outer housing towards the skin tensioner and causing the outer housing to move towards the leading end of the inner housing against the skin and against a force from the tensioning spring until the inner housing is in the firing position, wherein the force from the skin tensioning spring causes the skin to stretch in front of the nozzle; and

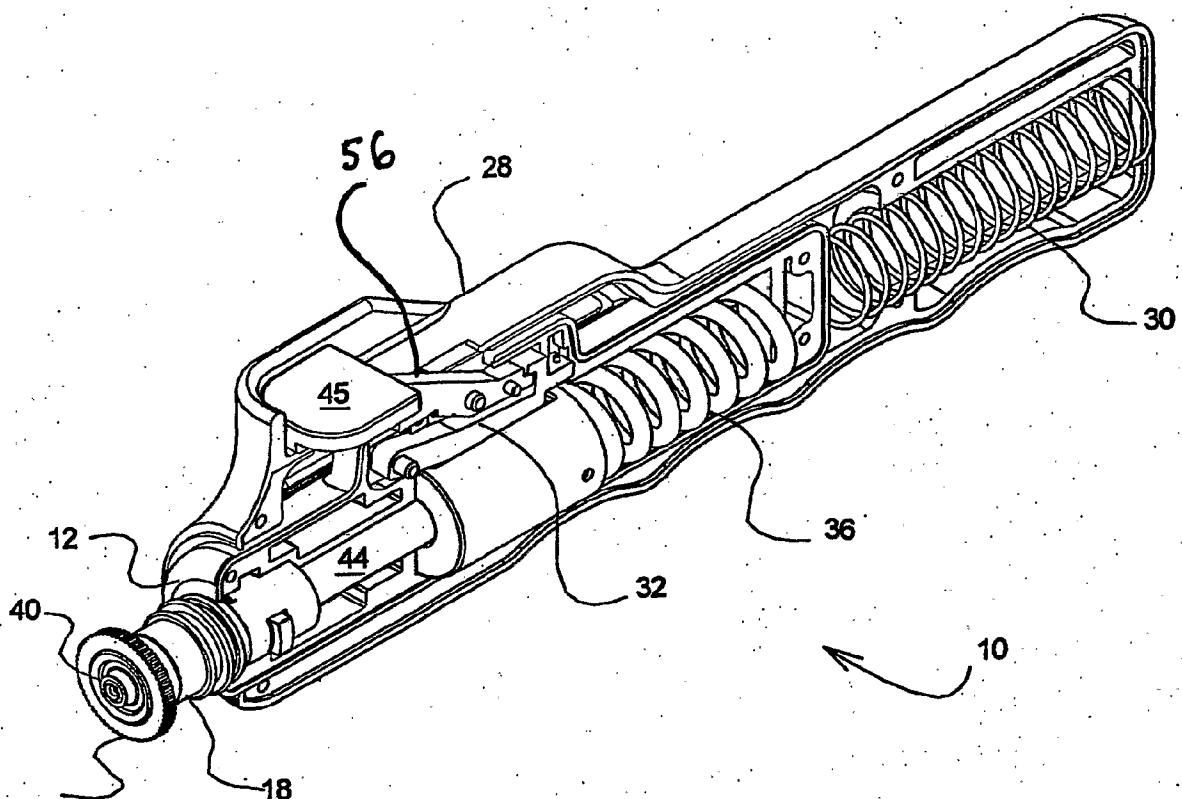
pressing the trigger to release the ram, wherein the ram forces the plunger through the cavity in the vial ejecting the fluid from the vial through the nozzle into the area.

16. The method described in claim 15, wherein an injection delivery is positioned between the trailing end of the inner housing and the spring powered ram, and further comprising the step of moving the spring powered ram towards the trailing end of the inner housing to compress the injection delivery spring and move the spring powered ram towards the cocked position.

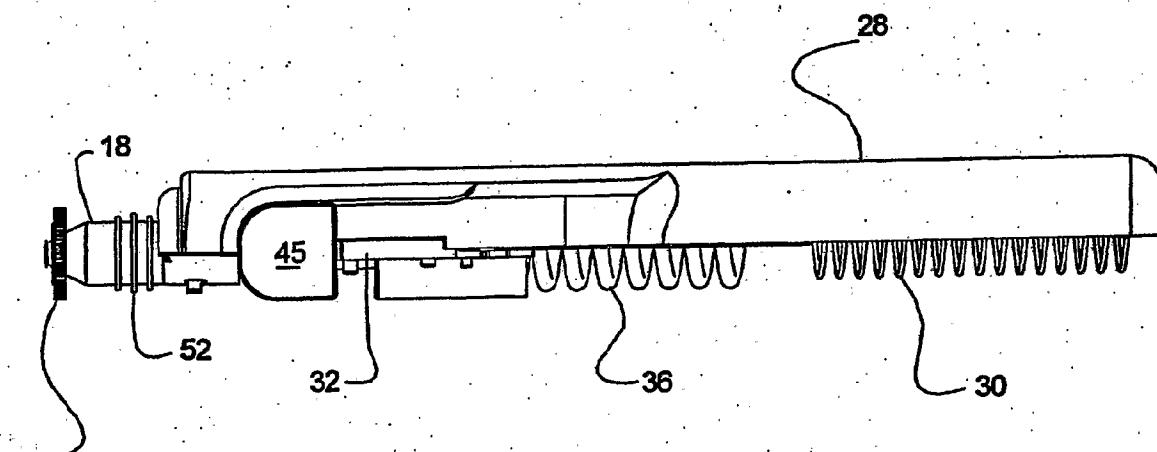
17. The method described in claim 16, wherein said skin-tensioning spring has a lower stiffness than said injection delivery spring.

18. The method described in claim 17, wherein said skin-tensioning spring and said injection delivery spring are disposed in series.

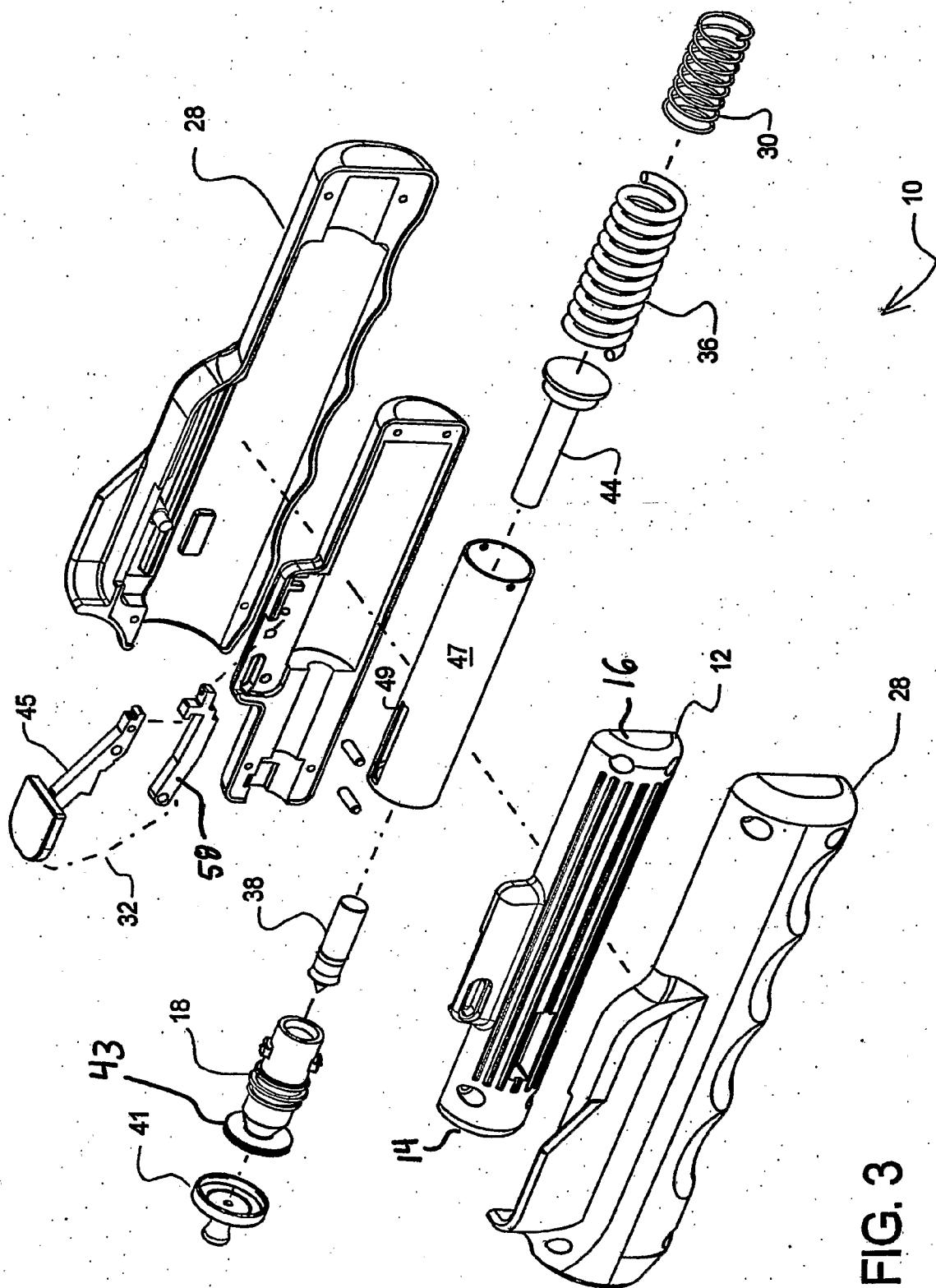
19. The needle-less injection device of claim 1, further comprising an injection delivery spring positioned between the trailing end of the inner housing and the spring powered ram, wherein when the spring powered ram is moved towards the trailing end of the inner housing the injection delivery spring is compressed to move the spring powered ram towards the cocked position.



43 Fig. 1



43 Fig. 2



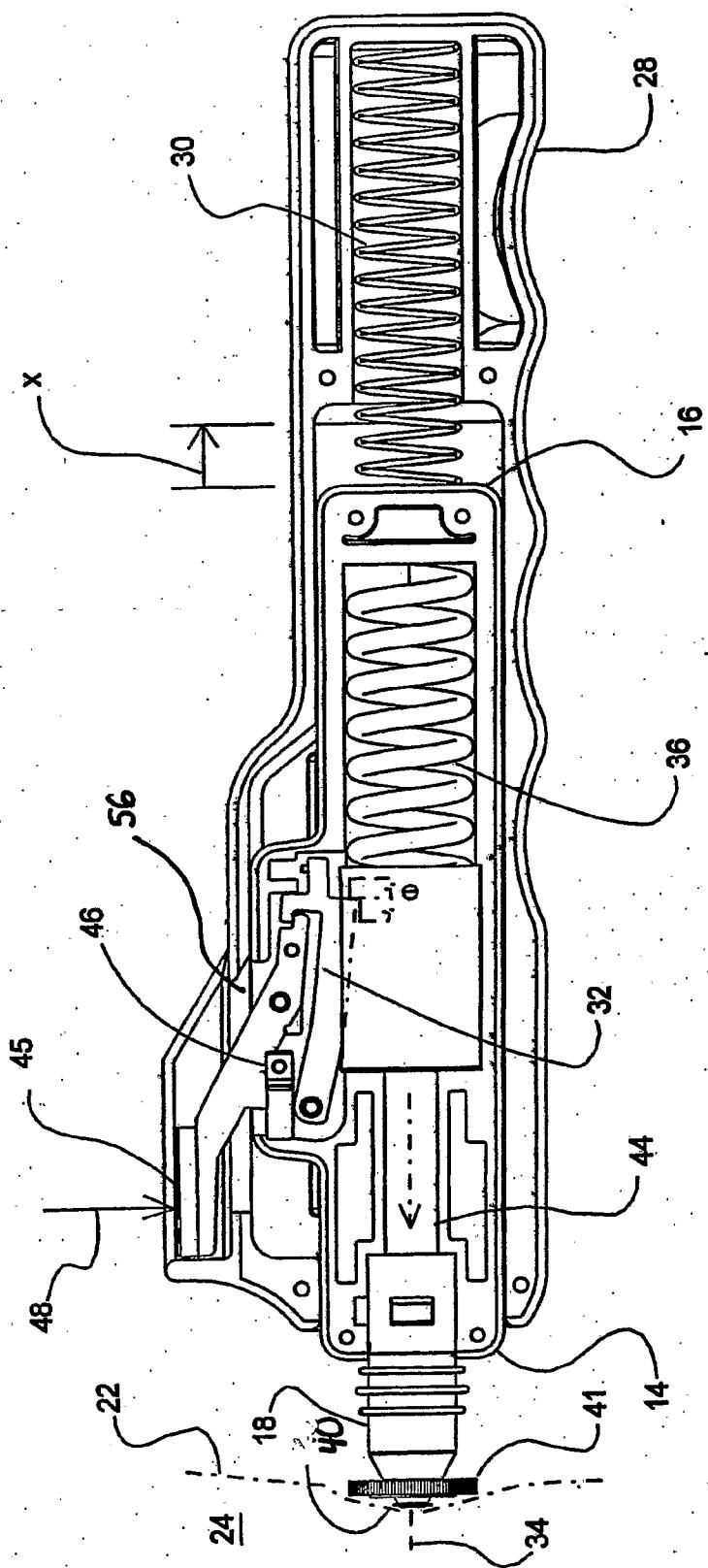


Fig. 4

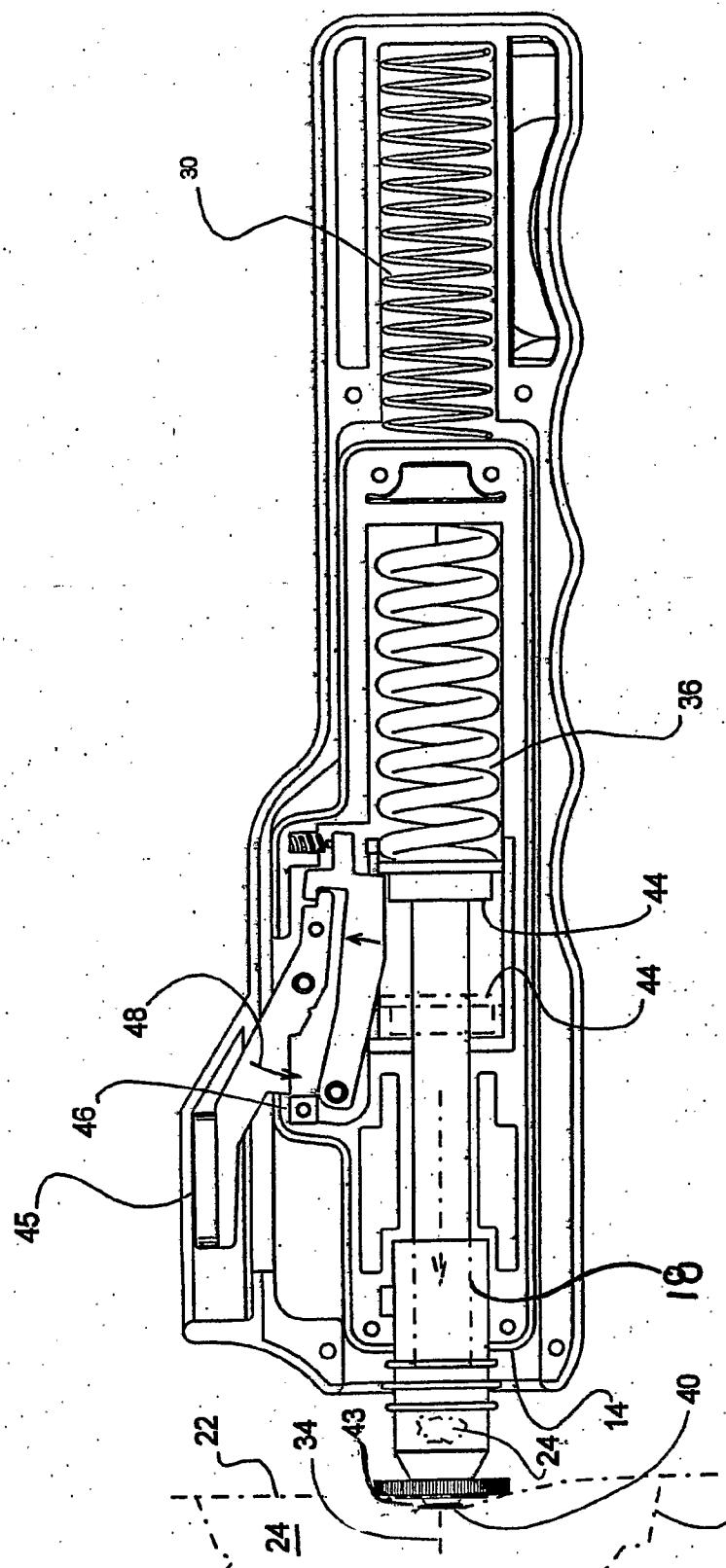
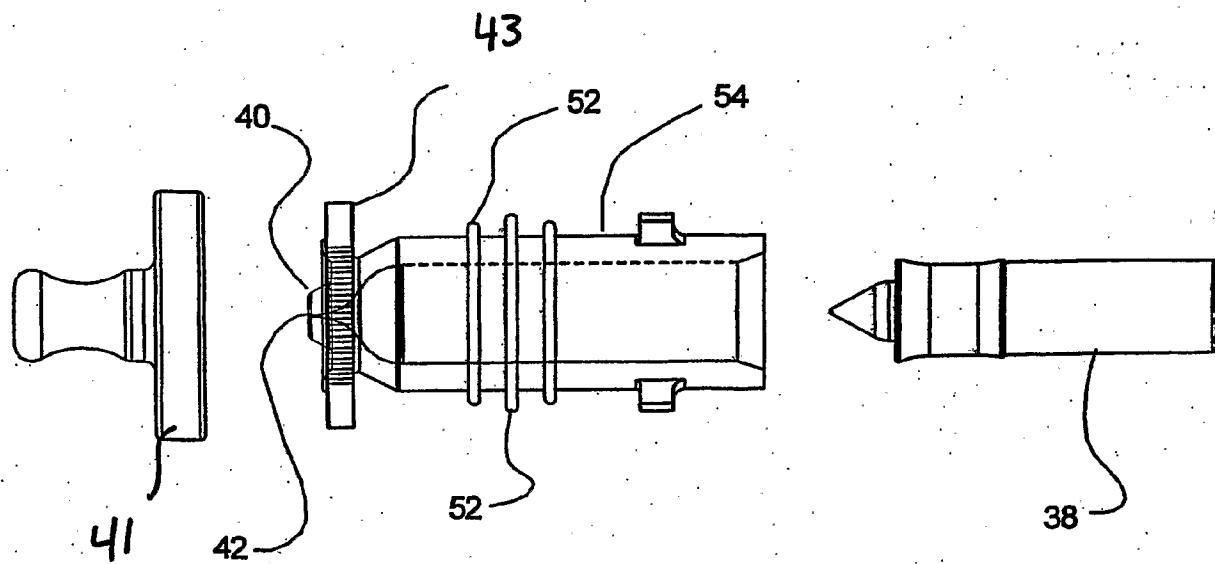
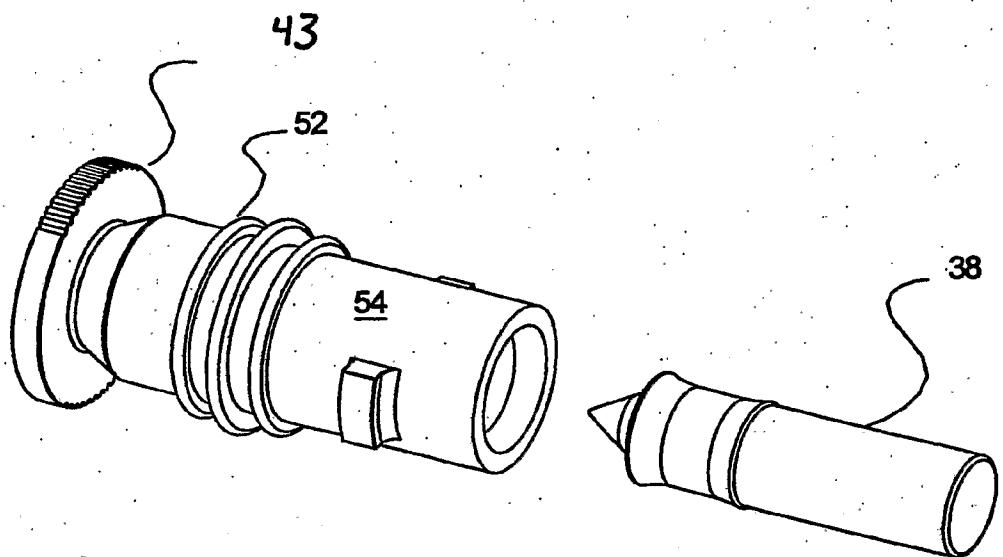
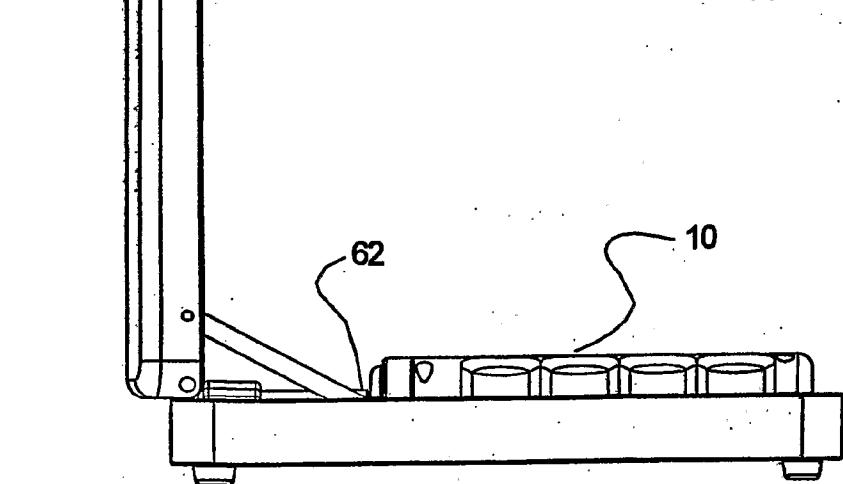
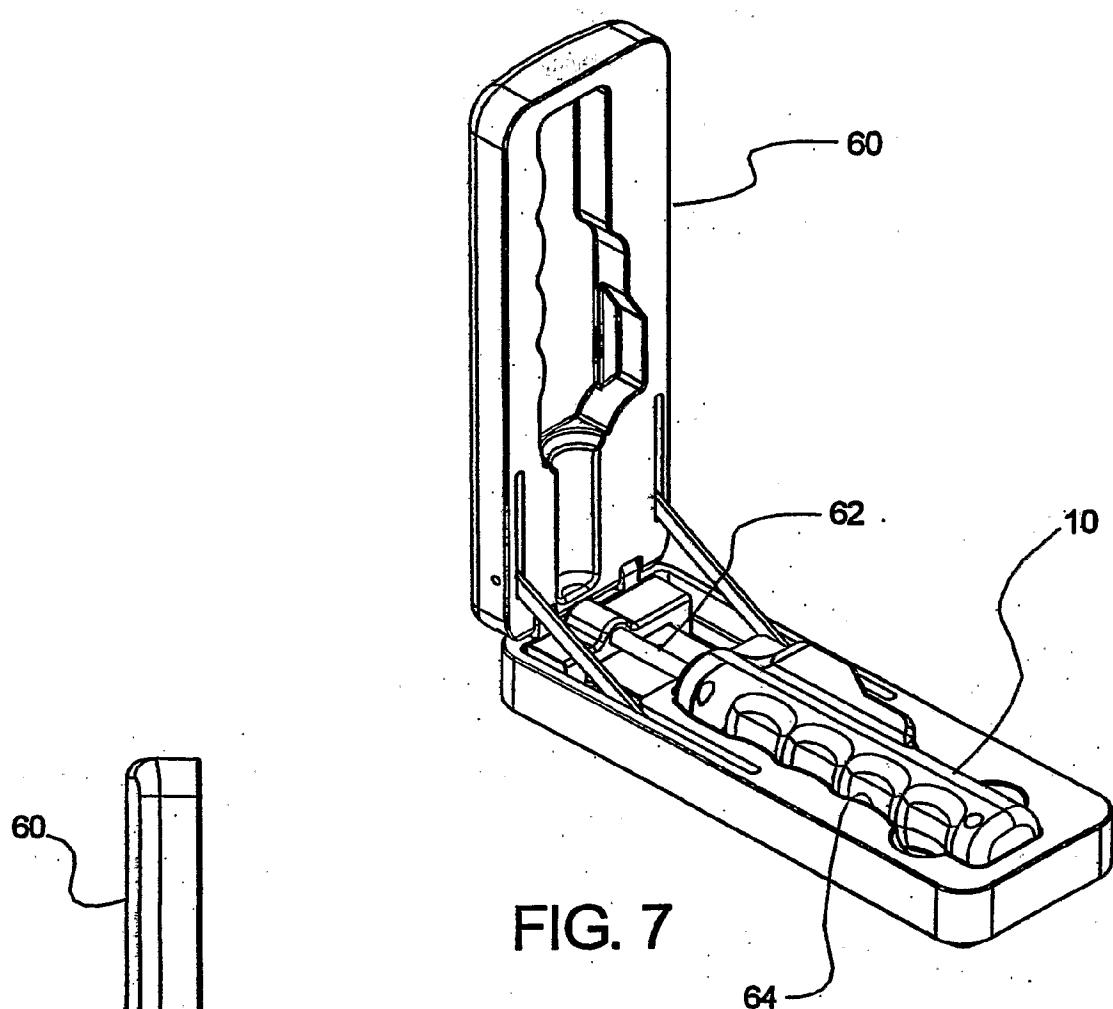


Fig. 5

**FIG. 6B****FIG. 6A**



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/46041

A. CLASSIFICATION OF SUBJECT MATTER
IPC: A61M 5/30(2006.01)

USPC: 604/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/68-72, 187, 218, 131, 133, 134, 135, 140, 141, 156, 157

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,569,189 A (Parsons) 29 October 1996 (29.10.1996), see the entire patent.	1-19
A	US 4,103,684 A (Ismach) 01 August 1978 (01.08.1978), see the entire patent.	1-19

Further documents are listed in the continuation of Box C.

See patent family annex.

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